**IN THE UNITED STATES DISTRICT COURT**

**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| | : | **CIVIL ACTION** |
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| **IN RE OCUGEN, INC.** | : | **Master File No. 21-2725** |
| **SECURITIES LITIGATION** | : | |
| | : | |

**MEMORANDUM**

**KENNEY, J.** **MARCH 3, 2023**

## I. INTRODUCTION

Lead Plaintiff Andre Galan Bernd Benayon ("Plaintiff"), individually and on behalf of a putative class, brings three claims against Ocugen, Inc. ("Ocugen" or the "Company"), Mr. Musunuri (Ocugen's Co-Founder, CEO, and Chairman), and Dr. Forrest (a member of Ocugen's Vaccine Scientific Advisory Board and Acting Chief Medical Officer) (collectively, "Defendants" or, alternatively, "Individual Defendants" as to Mr. Musunuri and Dr. Forrest)[1] alleging securities fraud under Section 10(b) of the Exchange Act, 15 U.S.C. § 78(j)(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, against all Defendants (Count I); control person liability under Section 20(a) of the Exchange Act, 15 U.S.C. § 78(t), against Individual Defendants (Count II); and insider trading under Section 20A of the Exchange Act, 15 U.S.C. § 78t-1(a), against Mr. Musunuri (Count III). ECF No. 28. Before the Court is Defendants' fully briefed and argued Motion to Dismiss.

[1] Ocugen's former CFO, Sanjay Subramanian, was named in the Amended Complaint but was dismissed by stipulation on August 17, 2022. ECF No. 42.

ECF Nos. 41, 43, 44. For the reasons set forth below, the Court will grant Defendants' Motion and dismiss this case. An appropriate order will follow.

## II. BACKGROUND

Ocugen is a biopharmaceutical company that was founded by Mr. Musunuri and non-party Professor Uday Kompella in 2013 to develop treatments for rare sight-threatening diseases. ECF No. 28 at 47. As of early 2019, the Food and Drug Administration ("FDA" or the "Agency") had not approved any of Ocugen's drug treatments, and the company did not have any products approved for sale. *Id.* at 47–48. In fact, Ocugen was a failing company; between 2013 and 2020 the Company saw only $50,620 in total revenue and in both 2019 and 2020 the Company incurred over $20 million in net losses. *Id*. at 97. Accordingly, from 2013 through December 2020, the Company was able to fund its operations only by raising approximately $90 million from the sale of common stock, warrants, and convertible notes, and by securing debt. *Id.*

On September 27, 2019, as a result of a reverse-merger, Ocugen was publicly listed under the ticker symbol "OCGN" on the NASDAQ which has a minimum trading price of $1.00 per share. *Id.* at 8, 47–48, 97. However, between September 2019 and November 25, 2019, Ocugen's stock declined in value from $2.85 to $0.266 per share. *Id.* at 48. By June 2020, Ocugen had abandoned efforts of a "promising" product and had terminated one-third of its employees. *Id.* at 1. By July 2020, Ocugen's stock had declined further to $0.196 per share. *Id.* at 48. In November

2020, the Company reported via its SEC Form 10-Q that there was "substantial doubt" that Ocugen would be able to continue its business operations. *Id.* at 97.

On December 22, 2020, following the emergence of COVID-19 as an unprecedented global pandemic, Ocugen announced[2] that it had executed a letter of intent to partner with Bharat Biotech International Limited[3] ("Bharat") to develop and bring to the United States market the COVAXIN vaccine. *Id.* at 2. COVAXIN, which was developed in collaboration with the Indian Council for Medical Research and the Indian National Institute of Virology, is an inactivated whole-virion vaccine that was ultimately approved for use in India in January 2021. *Id.* at 40, 42. An inactivated virus vaccine is one in which the virus is chemically inactivated and the pathogen's "outer shell," which is unable to cause infections, is injected into the body. *Id.* at 40. This triggers an immune response to the proteins on the inactivated "shell," also known as the antigens.[4] *Id.* The inactivated virus approach is an "established technology" that has been successfully utilized by Bharat, among others. *Id.* COVAXIN was a marked shift from the Company's previous focus on blindness diseases and the Company's priorities shifted accordingly.[5]

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[2] The press release announcing the partnership was entitled "Ocugen and Bharat Biotech to Co-Develop COVAXIN™, a Whole-Virion Inactivated COVID-19 Vaccine, for the Market." ECF No. 28 at 50. Indeed, that COVAXIN was an inactivated virus vaccine has been at the forefront of Ocugen's marketing campaign from day one.

[3] Bharat is an Indian biotechnology company. *Id.* at 2.

[4] The inactivated virus approach differs from the mRNA or adenovirus vector technologies used in other COVID-19 vaccines developed by Pfizer Inc. and BioNtech SE, Moderna, Inc., and Johnson & Johnson. *Id.* at 40.

[5] For example, Mr. Musunuri's compensation model changed to adopt this new priority. In March 2021, Ocugen's Board of Directors modified its previous "cash bonus" framework and revised performance-based metrics to encompass COVAXIN; one of Mr. Musunuri's new performance metrics for both cash and option incentive bonuses was to file an EUA application for COVAXIN by the end of 2021. *Id.* at 101. Additionally, Mr. Musunuri's compensation increased from approximately $1.5 million in 2020 to $8 million in 2021. *Id.* at 102.

**a. The FDA's Guidance on COVID-19 Vaccines**

On March 27, 2020, the U.S. Department of Health and Human Services declared that the FDA could issue emergency use authorization ("EUA") for unapproved drugs, or unapproved uses of approved drugs, under certain circumstances[6] rather than adhering to the typical, and more rigorous biologics license application ("BLA") process. *See id.* at 15. The EUA process affords the FDA more flexibility in authorizing a drug for use and, importantly, allows for EUA before the conclusion of Phase III clinical trials. *Id.*; 21 U.S.C. § 360bbb–3(c)(2). To aid in the EUA process, the FDA provided non-binding guidance to COVID-19 vaccine developers throughout the height of the pandemic. *Id.* 16–20, 23–26; *see* 21 C.F.R. § 10.115(d)(1) ("Guidance documents do not establish legally enforceable rights or responsibilities [and] do not legally bind the public or FDA."). Although the guidance documents represented the "current thinking" of the FDA, each also contained a disclaimer explaining that vaccine developers could "use an alternative approach if it satisfie[d] the requirements of the applicable statutes and regulations." ECF No. 41-1 at 6.

Two of the guidance statements at issue relate in relevant part to the diversity of clinical trial participants. Specifically, guidance published in June 2020 "encourage[d] the inclusion of diverse populations in all phases of vaccine clinical development" which included racial and ethnic minorities, the elderly, those with comorbidities, pregnant persons, those of childbearing age, and children. ECF No. 41-15 at 15. Similar sentiments were reiterated in a November 2020 guidance

[6] The FDA was permitted to issue an EUA upon a finding that: (i) based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it was reasonable to believe that the product may be effective; (ii) the known and potential benefits of the product outweighed the known and potential risks of the product; and (iii) there was no adequate, approved, and available alternative to the product. ECF No. 28 at 24; 21 U.S.C. § 360bbb–3(c)(3). The binding authority did not place any requirements on vaccine developers with respect to the demographic representation of clinical trials, nor did they foreclose EUAs to specific types of vaccines.

which provided that inadequate participant diversity "can lead to insufficient information pertaining to medical product safety and effectiveness for product labeling." ECF No. 28 at 23. The guidance further emphasized that different responses to medical products may be observed in racially or ethnically distinct subgroups of the United States population and, therefore, the FDA "recommend[ed]" that trials capture "data on race and ethnicity [which] may assist in identifying population-specific" responses.[7] *Id.*

The FDA also issued guidance documents in October 2020, February 2021, and May 2021, with each guidance superseding the former. *Id.* at 19, 23–27. In each, the FDA described its authority to issue EUAs and emphasized the importance of early and frequent communication with the FDA throughout vaccine development. *Id.* The FDA further emphasized that EUA decisions would be made on a case-by-case basis "considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product." *Id.*

In the October 2020 guidance, the FDA stated that EUA considerations would be based on "data from at least one well-designed Phase III clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner." *Id.* at 25. The February 2021 guidance was updated to address emerging COVID-19 variants but did not relax the Agency's prior recommendations with respect to EUA applications. *Id.* at 18–25.

[7] Despite such guidance statements, the FDA pointed out that it had never "had requirements for demographic composition of data to support licensure of a vaccine and . . . it would be very difficult to outline such requirements for EUA." ECF No. 28 at 22. Indeed, this statement captures the EUA framework: the guidances reflected the best practices or ideal scenario but did not impose strict requirements on vaccine sponsors in light of the emergency situation.

Several vaccines were granted EUAs by the FDA in late 2020 and early 2021: (i) an mRNA vaccine developed by Pfizer Inc. and BioNTech SE (collectively "Pfizer") on December 11, 2020; (ii) an mRNA vaccine developed by Moderna, Inc. ("Moderna") on December 18, 2020; and (iii) an adenovirus vector vaccine developed by Johnson & Johnson on February 27, 2021. *Id.* at 26–35. As a result, in May 2021, the FDA stated via guidance that it "may decline to review and process further EUA requests other than those vaccines whose developers have engaged in an ongoing manner with the Agency during the development of their manufacturing process and clinical trials program." *Id.* at 26. The guidance issued was generally applicable to the development of all COVID-19 vaccines, though the May 2021 guidance also included an appendix addressing concerns that previously authorized vaccines might have reduced efficacy against subsequent variants such as those arising in the United Kingdom and South Africa. ECF No. 41-20 at 22.

**b. COVAXIN's Progress Towards EUA and the Impact on Ocugen Stock**

COVAXIN development began on May 9, 2020. *Id.* at 40. Clinical trials lagged behind those of other COVID-19 vaccines: the first participant was enrolled in COVAXIN's Phase III trial on November 11, 2020 – just one month prior to the FDA's grant of EUA for the Pfizer vaccine. *Id.* at 42. Shortly thereafter, and prior to any efficacy or safety data from the Phase III trial, the Drug Controller General of India granted COVAXIN accelerated approval on January 3, 2021. *Id.* Clinical trials progressed throughout the class period. On March 3, 2021, Bharat released initial Phase III data which claimed 81% efficacy in preventing COVID-19 in those without prior infection. *Id.* at 46. According to Defendants, the India-based trial represented a diverse cross-section of the Indian population based on age, weight, body mass index, underlying conditions, and economic and social factors. *Id.* at 76. Ultimately, in July 2021, Bharat described the Phase III

trial as showing that COVAXIN had a 77.8% efficacy against symptomatic COVID-19 and 63.6% efficacy against asymptomatic infections.[8] *Id.* at 47.

On February 2, 2021, Ocugen announced that it had executed a definitive agreement with Bharat for the commercialization of COVAXIN and that it planned to pursue an EUA for the vaccine. *Id.* at 51. In connection with this announcement, Ocugen projected that it would distribute 100 million doses of COVAXIN in the United States during 2021. *Id.* That same day, Ocugen's stock increased from $1.81 per share on February 1, 2021, to $3.26 per share on February 2, 2021. *Id.* at 53. Ocugen's SEC filings, filed February 5, 2021, proclaimed that the Company was in "pre-EUA discussions with the FDA." *Id.* Ocugen provided that it planned to file for EUA in the first half of 2021 to meet its goal of 100 million doses distributed in 2021. *Id.* According to Ocugen, COVAXIN had "potential for significant revenues" in 2021. *Id.* Between February 5, 2021 and February 8, 2021, Ocugen stock increased further from $5.25 to $15.81 per share and Ocugen saw significant proceeds as a result. *Id.* at 53–54. For example, in April 2021, Ocugen announced the closing of a $100 million direct stock offering that resulted in $93.4 million net proceeds to the Company. *Id.* at 54.

In the four months following Ocugen's initial announcement that it would seek EUA for COVAXIN, Defendants maintained their projected timeline and spoke optimistically of COVAXIN's path towards EUA application submission. Indeed, Plaintiff points to fifteen such representations as the basis of this action. *See* ECF No. 41-3 (organizing each statement alleged in

[8] Throughout the Phase III trial, allegations surfaced claiming that there were insufficient measures to ensure that the COVID-19 virus was fully inactivated, such that it would not infect recipients, and criticizing the ethical and clinical practices employed in the trial. ECF No. 28 at 43–46.

chart format). These statements can be grouped into four categories: (i) SEC filings and related website postings; (ii) news articles; (iii) press releases; and (iv) investor calls.

As an initial matter, Plaintiff points to five Form 8-Ks and related slide decks filed with the SEC and six related postings on Ocugen's website which, despite being circulated at different times[9], are substantively identical. *Id.* at 63–64, 67–68, 74–75, 79–80, 85–86, 89. The relevant language in each provided that Ocugen: (i) was in "pre-EUA discussions with the FDA"; (ii) was targeting 100 million doses per year beginning in 2021; (iii) planned to file an EUA application with the FDA in the first half of 2021; (iv) planned to make COVAXIN shots available in the first half of 2021; and (v) anticipated that the COVAXIN vaccine had "potential for significant revenues this year." *See generally*, *id.* The slide decks varied slightly, but each included to-date progress of the COVAXIN development and trials as well as projections for next steps. *Id.* Each slide deck was also posted to Ocugen's website.[10] *Id.*

In a February 2, 2021 press release announcing the definitive agreement with Bharat, Ocugen provided that it would have "rights to the vaccine candidate and [would] be responsible for clinical development, regulatory approval (including EUA) and commercialization for the [United States] market." *Id.* at 51. The press release specified that Bharat would "supply initial doses to be used in the [United States] upon Ocugen's receipt of an EUA" and that Ocugen management had initiated discussions with the FDA. *Id.*

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[9] Ocugen filed the relevant materials with the SEC on February 5, March 5, March 31, May 7, and May 19 of 2021.

[10] In the case of the May 19, 2021 website posting, it remained on the website after the FDA issued revised guidance on May 25, 2021 indicating that the Agency would be more discerning in granting additional EUAs.

An article published by the *American Bazaar* on March 2, 2021 quoted Mr. Musunuri as stating that Ocugen had "initiated discussions with the FDA and BARDA[11] to develop the regulatory path for the EUA and eventual full approval in the United States for Covaxin." *Id.* at 65–66. According to the article, Mr. Musunuri "expect[ed] efficacy data early in March and [that Ocugen would] proceed full speed ahead at that point towards [EUA]." *Id.* Mr. Musunuri reiterated that Ocugen was "aiming for 100 million doses" in 2021. *Id.* Further, on March 15, 2021, *Reuters* published an article entitled "Ocugen seeks to sell 100 million Indian vaccine doses in U.S. in 2021." *Id.* at 68. Mr. Musunuri affirmed these plans and, according to *Reuters*, when asked about the FDA he stated that "they're fine with the way the interim analysis is being done." *Id.* at 69.

On March 18, 2021, Mr. Musunuri spoke about Ocugen's recent partnership with Bharat on an investor call. In his opening remarks, Mr. Musunuri described COVAXIN as "provid[ing] an excellent opportunity . . . to enter the infections disease market" because it was "different from other COVID-19 vaccine options currently authorized for emergency use in the United States" which "rely on new mRNA, or adenovirus technology, while COVAXIN utilizes a traditional approach as an advanced stage whole-virion inactivated vaccine." ECF No. 41-37 at 4. He went on to describe the Phase III trials and noted that the Company was "in active discussions with the FDA" and that "[b]ased on [the] discussions," planned to file an EUA application in April 2021. *Id.*

Subsequently, on March 31, 2021, Ocugen held a virtual "fireside chat" to discuss the development of COVAXIN. During the fireside chat, Ocugen theorized that inactivated virus

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11 The Biomedical Advanced Research and Development Authority ("BARDA") is an office of the U.S. Department of Health and Human Services that worked with the FDA in the COVID-19 vaccine development and approval process.

vaccines might be more likely to provide coverage against COVID-19 than other alternatives. ECF No. 41-1 at 4. Dr. Forrest spoke about the international standards informing COVAXIN's clinical trials and the diversity of Phase III trial participants. ECF No. 28 at 76. He noted that the participants included a diverse subset of the Indian population with respect to age, weight, body mass index, underlying conditions, and social and economic circumstances. *Id.* Mr. Musunuri added that he thought the data would be translatable at this stage "in the middle of the pandemic." *Id.* at 77. He further explained that the first step towards EUA was filing a Master File, which Ocugen did on March 26, 2021, and that Ocugen was working towards the second step of "filing the EUA when [the Company had] sufficient efficacy from the clinical trial . . . and also the safety data" required. *Id.* at 77, 87.

On May 7, 2021, Mr. Musunuri again represented the Company on an investor call. Mr. Musunuri reiterated that Ocugen had submitted a Master File to the FDA and was finalizing the EUA application, though it was "taking longer than anticipated." ECF No. 41-23 at 4. During the question-and-answer portion of the call, Mr. Musunuri was asked what, if anything, the FDA had said "about wanting to see vaccine data for U.S. patients before allowing [the EUA application] to move forward." *Id.* at 7. Mr. Musunuri replied that the FDA had not said anything to date. *Id.* Additionally, with respect to the process of submitting an EUA application, Mr. Musunuri indicated that Defendants were "following FDA guidance." *Id.* at 8 (describing the process of submitting a Master File and incorporating feedback from the FDA prior to EUA submission). Also on May 7, Ocugen issued a press release providing that the Company "continue[d] to make progress toward [EUA] for COVAXIN" and had "submitted key information and data to date as a Master File for FDA review prior to a planned EUA application" pending additional data from the Phase III trial. *Id.* at 82.

Following the FDA's May guidance indicating that it would prioritize EUAs for those developers that had been engaged in an ongoing dialogue with the FDA, on May 26, 2021, Ocugen issued a press release confirming the Company's plan to submit an EUA application in June and stating that the Company did not believe that the guidance raised any concerns for COVAXIN. In fact, Ocugen "believe[d] that the FDA's new guidance confirms that Ocugen continues to meet all criteria for submission of an EUA." *Id.* at 87. Moreover, Mr. Musunuri was not concerned by the updated guidance because Ocugen had "been in discussions with the FDA since [the year prior]"—precisely what the FDA contemplated as to additional EUAs. *Id.* at 55. Dr. Forrest also provided that he read the guidance to "refer[] specifically to vaccines based on the spike protein" rather than inactivated virus vaccines such as COVAXIN. *Id.*

In the statements at issue, Ocugen repeatedly projected that 100 million doses of COVAXIN would be distributed in 2021, leading to significant profitability. Ultimately, however, Ocugen's optimism did not bear out. As instructed by the FDA, Ocugen submitted a Master File to the Agency prior to submitting an EUA application. *Id.* at 56. Upon review of the Master File, the FDA recommended (at an unspecified date in June 2021) that Ocugen pursue a BLA submission rather than an EUA. *Id.* Accordingly, prior to market open on June 10, 2021, Ocugen announced that it would pursue a BLA for COVAXIN, which necessarily extended the anticipated timeline for vaccine approval and distribution. *Id.* at 56. In response to this news, Ocugen's stock price declined from $9.31 per share on June 9, 2021 to $6.69 per share on June 10, 2021.[12] *Id.* at 57. Notably, Mr. Musunuri was somewhat shielded from the full effects of the declined stock

[12] According to Plaintiff, this resulted in a loss of market capitalization exceeding $500 million. *Id.* at 106. Additionally, financial analysts at Cantor Fitzgerald and Chardan Research reduced their target price for Ocugen by $7 and $3.50 per share, respectively. *Id.*

because on May 3, June 7, and June 8, he sold thousands of Ocugen shares pursuant to a 10b5-1 trading plan for total proceeds of $3,123,536. *Id.* at 100; ECF No. 41-1 at 9.

## III. PROCEDURAL HISTORY

The initial class action complaint alleging violation of securities laws and premised on the above-described facts was filed on June 17, 2021 before the Honorable Judge Jones. ECF No. 1 The Private Securities Litigation Reform Act ("PSLRA"), requires the plaintiff who files the initial action to publish a notice informing the purported class of the pending litigation and class members' right to file a motion for appointment as Lead Plaintiff. 15 U.S.C. § 78u-4(a)(3)(A)-(B). Subsequently, within sixty days of the notice, any member of the purported class may move the court to serve as Lead Plaintiff. *Id.* Here, four class members sought appointment of this role. ECF No. 7–10. Following full briefing on the matter, Judge Jones consolidated the four cases and appointed Mr. Benayon as Lead Plaintiff on March 31, 2022. ECF No. 22.

Pursuant to a Joint Stipulation, Lead Plaintiff filed an Amended Complaint on June 13, 2022. ECF Nos. 23, 28. Therein, Plaintiff alleged securities fraud under Section 10(b) of the Exchange Act, 15 U.S.C. § 78(j)(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, against all Defendants (Count I); control person liability under Section 20(a) of the Exchange Act, 15 U.S.C. § 78(t), against Individual Defendants (Count II); and insider trading under Section 20A of the Exchange Act, 15 U.S.C. § 78t-1(a), against Mr. Musunuri (Count III). ECF No. 28. On June 21, 2022, the consolidated case was transferred to the Honorable Judge Schiller and then again, on June 24, 2022, to this Court. ECF Nos. 30–31. Pursuant to a stipulated scheduling agreement, Defendants filed the instant Motion to Dismiss on August 12, 2022. ECF No. 41. Plaintiff filed a Response on October 11, 2022 to which Defendants Replied on November 9, 2022. ECF Nos. 43–44. The Court held oral argument on Defendants' Motion on January 23, 2023. ECF No. 50.

Having been fully briefed and argued, Defendants' Motion to Dismiss is now ripe for consideration.

## IV. STANDARD OF REVIEW

To survive a motion to dismiss, the complaint must contain sufficient facts "to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint is plausible on its face when the plaintiff pleads factual contention that "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Courts are required to "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). However, the complaint must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

Because Plaintiff alleges securities fraud, he must also satisfy the heightened pleading standards set forth in Fed. R. Civ. P. 9(b) and the PSLRA. Under Rule 9(b), Plaintiff must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Under the PSLRA, the Complaint must specify each allegedly misleading statement, why the statement was misleading, and all facts supporting that belief with particularity. *Avaya, Inc.*, 564 F.3d at 252–54 (parties must plead "the who, what, when, where and how" of the alleged fraud); 15 U.S.C. § 78u–4(b)(1). Additionally, for each act or omission alleged, Plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind [scienter]." 15 U.S.C. § 78u-4(b)(2)(A). Accordingly, "[f]ailure to meet the threshold pleading requirements .

. . justifies dismissal apart from Rule 12(b)(6)." *California Public Employees' Retirement System v. Chubb Corp.* ("*CALPERS*"), 394 F.3d 126, 145 (3d Cir. 2004).

As is also true generally, "courts must consider the complaint in its entirety, as well as . . . documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Inst. Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007)). The Court may take judicial notice of matters of public record, such as SEC filings, and documents "integral to or explicitly relied upon in the complaint." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014).[13]

## V. DISCUSSION

For the reasons set forth below, the Court finds that Plaintiff fails to state a claim under Section 10(b) of the Exchange Act and Rule 10b-5 thereunder and will dismiss Count I. Accordingly, because a viable claim of securities fraud is necessary to support Plaintiff's other claims, Counts II and III will be dismissed as well.

### a. Section 10(b) of the Exchange Act and Rule 10b-5(b) (Count I)

Section 10(b) forbids the "use or employ, in connection with the purchase or sale of any security . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). SEC Rule 10b-5 implements section 10(b) by, *inter alia*, declaring it unlawful to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statement made, in the light of the circumstances

[13] Defendants attach several exhibits to their motion and reply. The Court deems it appropriate to take judicial notice of three subsets of those documents: (i) those containing the statements and omissions Plaintiff alleges as the basis of this action; (ii) public SEC filings; and (iii) the relevant FDA guidance documents.

under which they were made, not misleading, in connection with the purchase or sale of any security. 17 C.F.R. § 240.10b-5(b). Accordingly, to state a claim under Section 10(b) and Rule 10b-5(b) thereunder, Plaintiff must adequately allege: (i) a material misrepresentation or omission; (ii) scienter; (iii) a connection between the misrepresentation or omission and the purchase or sale of a security; (iv) reliance; (v) economic loss; and (vi) loss causation. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277 (3d Cir. 2010). As previously stated, these allegations must be pleaded with particularity to satisfy the PSLRA. See 15 U.S.C. § 78u-4.

Defendants argue that Plaintiff fails to state a claim under Section 10(b) and Rule 10b-5(b) because: (i) the Amended Complaint fails to allege an actionable misrepresentation or omission; (ii) the Amended Complaint does not plead scienter with particularity; (iii) the Amended Complaint has failed to plead loss causation; and (iv) the PSLRA's safe harbor should apply. Because the Court finds that the Amended Complaint fails as to the first element, material misrepresentation or omission, it need not address subsequent elements.

**i. Legal Standard (Material Misrepresentation or Omission)**

Section 10(b) and Rule 10b-5(b) "do not create an affirmative duty to disclose any and all material information," however, "[o]nce a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading." *Williams v. Globus Med., Inc.*, 869 F.3d 235, 241 (3d Cir. 2017). Accordingly, "a plaintiff must show that the defendant made a statement that was '*misleading* as to a *material* fact.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (emphasis original). The Court determines materiality as of the date of the alleged misstatement or omission, not with the benefit of hindsight. *See In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002). Because of the heightened pleading requirements, Plaintiff must "specify

each allegedly misleading statement and the reasons why the statement is misleading." *Avaya, Inc.,* 564 F.3d at 252 (3d Cir. 2009) (citation omitted); 15 U.S.C. § 78u–4(b)(1). In other words, Plaintiff must both "identify Defendants' allegedly false and misleading statements with particularity" *and* specify with particularity the "true facts" that demonstrate how each statement or omission was indeed false or misleading at the time the statement was made. *See CALPERS*, 394 F.3d at 145; *Williams*, 869 F.3d at 244.

Pleading "true facts" generally requires that the plaintiff "cit[e] contemporaneous sources" rather than rely on "conjecture based on subsequent events." *Williams*, 869 F.3d at 244; *CALPERS*, 394 F.3d at 155 (allegations based on conjecture are "undisputedly insufficient"); *In re Discovery Labs. Sec. Litig.*, No. 06-cv-1820, 2006 WL 3227767, at *9 (E.D. Pa. Nov. 1, 2006) ("An omission 'that is misleading *only in hindsight*' cannot form the basis for a securities fraud claim." (citation omitted) (emphasis original)). This is traditionally done by relying on confidential witnesses or documentary evidence such as internal memoranda to establish the reason(s) why the statement or omission was false or misleading at the time it was made. Adequately pleading true facts is not just a formality; indeed, whether "true facts" are pled with particularity is of "paramount importance." *See CALPERS*, 394 F.3d at 145.

Moreover, Plaintiff must show not only a false or misleading statement or omission, but also "that the alleged misstatement or omission is material." *Fan v. StoneMor Partners LP*, 927 F.3d 710, 716 (3d Cir. 2019); *Basic Inc. v. Levinson*, 485 U.S. 224, 238 ("It is not enough that a statement is false or incomplete, if the misrepresented fact is otherwise insignificant."). An omitted fact is material if "there [is] a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc.*, 485 U.S. at 231–32 (citation omitted). The question of

materiality "typically presents a mixed question of law and fact," which is traditionally viewed as appropriate for the trier of fact. *Semerenko v. Cendant Corp.*, 223 F.3d 165, 178 (3d Cir. 2000). However, "complaints alleging securities fraud often contain claims of omissions or misstatements that are obviously so unimportant that courts can rule them immaterial as a matter of law at the pleading stage." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

In deciding materiality, courts look to whether the defendants "sufficiently disclosed facts and information that would render the alleged misrepresentations not misleading." *Fan*, 927 F.3d at 716–17 (holding statements identified as fraudulently misleading were "rendered immaterial given the pertinent disclosures"). Importantly, corporate puffery does not qualify as material because reasonable investors do not rely upon such platitudes or "consider [them] important in deciding how to [act]." *In re Aetna*, 617 F.3d at 283. Indeed, it is well settled that "'statements of subjective analysis or extrapolations, such as opinions, motives and intentions, or general statements of optimism' . . . 'constitute no more than puffery and are understood by reasonable investors as such.'" *Id.* (quoting *EP Medsystems, Inc. v. Echocath. Inc.*, 235 F.3d 865, 872 (3d Cir. 1999); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1427 (holding "vague expressions of hope by corporate managers" relating to future earnings or "optimism . . . that a trend will continue" are not actionable). Accordingly, "[s]uch statements, even if arguably misleading, do not give rise to a federal securities claim because they are not material." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999), *abrogated on other grounds by Tellabs, Inc.*, 551 U.S. 308 (2007). Therefore, where a representation "is so obviously unimportant to an investor that reasonable minds could not differ on the question of materiality, the representation or omission will be immaterial as a matter of law." *EP Medsystems, Inc.*, 235 F. 3d at 875.

### ii. The Statements Alleged

As described above, Plaintiff identifies fifteen statements as allegedly false and misleading. The Amended Complaint systematically marches through the fifteen statements and describes who made each statement, when and where each was made, and the substance of each. *See Avaya, Inc.*, 564 F.3d at 253 (parties must plead "the who, what, when, where and how" of the alleged fraud). Undoubtedly, Plaintiff has identified the allegedly false and misleading statements with particularity. However, Plaintiff fails to adequately allege that each was misleading or false as to a material fact at the time the statements were made.

#### 1. Plaintiff's "Overarching Omission" Theory

Plaintiff's case does not rely upon internal documents or confidential witnesses to establish true facts that conflict with Defendants' statements at issue. Instead, Plaintiff alleges that the EUA pathway was *never* meaningfully available to COVAXIN because Ocugen was not following the (non-binding) FDA guidance in *every* respect. *See* ECF No. 28; Jan. 26, 2023 Hr'g. 18:1-6 ("the overarching omission that makes all statements misleading . . . is the fact that there [was] always a duty to disclose [that] the fast-track EUA pathway . . . was not realistically available to Ocugen"); Jan. 26, 2023 Hr'g. 18:12-13 ("This omission is enough to sustain Plaintiff's entire complaint"); Jan. 26, 2023 Hr'g. 28:16-23 ("The overarching omission that makes all these statements identified in the amended complaint misleading is that Defendants failed to disclose to investors that they were banking on the FDA making an exception to key aspects of its own guidance and precedent."). Put differently, Plaintiff alleges that all fifteen statements were misleading because Ocugen failed to disclose that EUA was not possible unless the FDA made exceptions to its otherwise non-binding guidance. Yet there is no indication that the FDA's purported flexibility was required because, importantly, there is no credible allegation that, at the time Defendants'

statements were made, the FDA intended to *exclusively* extend EUA only to those vaccines that strictly adhered to every single parameter delineated in each and every *non-binding* guidance. Indeed, Plaintiff's theory requires a carve out of exceptions from binding requirements that did not exist.

In reality, the FDA included a disclaimer on each guidance document explaining that vaccine developers could pursue "alternative approach[es]" provided that they complied with the "applicable statutes and regulations." ECF No. 41-1 at 6. Additionally, the guidance documents included a header on every page noting that the document "[c]ontain[ed] [n]onbinding [r]ecommendations." *See, e.g.*, ECF No. 41-20. Further still, the guidance provided that the recommendations did "not have the force and effect of the law" and "should be viewed only as recommendations." *Id.* at 5–6. Indeed "[t]he use of the word should in FDA guidances means that something is suggested or recommended, **but not required**." *Id.* (emphasis added). Similar sentiments are reiterated throughout the guidances. For example, the FDA's position that it "*encourage[d]*" diverse clinical trials cannot be read as a mandate. ECF No. 41-15 at 15.

This situation differs from *Matrixx*, in which the Supreme Court held that a company's projection that revenue would increase was misleading because, at the time of such statements, the company had information indicating a significant risk to its leading revenue-generating product in the form of actual consumer complaints (*i.e.* the true facts) which it omitted. 563 U.S. at 47. Here, Plaintiff asks the Court to rely on hindsight to establish an overarching "fact" where one did not exist: that EUA was always effectively foreclosed to COVAXIN unless an "exception" was made. This argument fails from the start because the "overarching omission" turns upon transforming the

FDA's non-binding guidelines into strict requirements based only on hindsight.[14] The Court declines to make such a holding. *See In re Discovery Labs.*, 2006 WL 3227767, at *12 (failure to reveal that clinical protocols did not meet non-binding regulatory standards did not support a

[14] Even if the Court was persuaded by Plaintiff's theory of an "overarching omission" and that EUA was foreclosed to COVAXIN because of failure to follow every aspect of FDA guidance (unless an exception was made), the Amended Complaint fails in other respects. Plaintiff alleges three flaws with the development of COVAXIN: (i) that COVAXIN was an inactivated virus vaccine; (ii) that Defendants did not communicate with the FDA at every stage of the vaccine development process; (iii) lack of racial diversity in clinical trials.

First, at no point did the FDA affirmatively express a blanket prohibition on EUAs for inactivated virus vaccines like COVAXIN. At most, Plaintiff asserts that Operation Warp Speed did not include inactivated virus vaccines in its initial portfolio of vaccine candidates. ECF No. 28 at 11. However, Operation Warp Speed was a collective effort of several agencies and organizations and, at most, reflects the combined priorities of such organizations. *Id.* at 10. Thus, even if strict compliance with FDA guidelines was required (which it was not), Plaintiff has not alleged that inactivated virus vaccines fell outside of FDA guidance such that an "exception" was required.

Second, as to communications with the FDA, Plaintiff does not describe with any level of particularity the points in the vaccine-development process at which Defendants failed to adequately communicate with the FDA. *See, e.g.*, ECF No. 28 at 62. Indeed, the Amended Complaint elsewhere suggests that Defendants were engaged in at least some discussions with the FDA. *See, e.g.*, *id.* at 71, 87. Though "the normally rigorous particularity rule has been relaxed somewhat where the factual information is peculiarly within the defendant's knowledge or control," it is still true that "boilerplate and conclusory allegations will not suffice." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1418 (citations omitted). Here, Plaintiff's allegations that Defendants failed to communicate with the FDA are nothing more than boilerplate conclusory statements. Therefore, even if Plaintiff's theory as to an "overarching" omission of true facts was viable, Plaintiff has not alleged that Defendants required an exception to the FDA's guidance in this respect.

Third, as discussed *infra*, even if racial diversity was a necessary requirement for EUA, reasonable shareholders were empowered with all material facts: the nature of the FDA guidance and that COVAXIN trials were taking place in India and using Indian participants. Accordingly, disclosure of any "omitted" information would not have altered the total mix of information already available. *See Basic Inc.*, 485 U.S. at 231–32; *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015) (recognized by *Lungu v. Antares Pharma. Inc.*, No. 21-cv-1624, 2022 WL 212309 (3d Cir. Jan. 25, 2022) and *In re Amarin Corp. PLC Sec. Litig.*, 689 Fed. App'x 124 (3d Cir. 2017)).

securities fraud claim because plaintiff could not allege that "defendants knew for certain that the [agency] would not approve [drug]").

Further, because an affirmative duty to disclose all information exists only where the omitted information is necessary to make statements made not misleading, it necessarily follows that the alleged omission must be rooted in a material and discernable fact. *See In re Discovery Labs.*, 2006 WL 3227767, at *9 ("Failure to disclose a *fact* . . . can lead to liability under Rule 10b-5 . . ." (emphasis added)); *Basic Inc.*, 485 U.S. 231–32 (an omitted fact is material if there is "substantial likelihood that the disclosure of the omitted *fact* would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." (emphasis added)); 17 C.F.R. 240.10b-5(b) (it is unlawful to "omit to state a material *fact* . . ." (emphasis added)). That is not the case here, where the omission alleged—failure to adhere to every aspect of non-binding guidance guaranteed denial of EUA for COVAXIN—is speculative and rooted in conjecture rather than in fact. *See Williams*, 869 F.3d at 244 (no duty to disclose a terminated relationship with a distributor when, at the time a statement was made that loss of a distributor *could* negatively impact sales, no negative impact had yet occurred). Accordingly, Plaintiff's claim cannot be sustained based on the "overarching omission" alleged. [15]

[15] The Court's finding is bolstered by the fact that Defendants frequently and repeatedly disclosed facts and information that would render any alleged omissions not misleading. Importantly, disclosures present in SEC filings are sufficient to alert reasonable investors to relevant risks and render purported "omissions" immaterial. *Fan*, 927 F.3d at 716–17 (disclosures in 10-K filings were sufficient to counter information omitted in press releases); *Ieradi v. Mylan Laboratories, Inc.*, 230 F.3d 594, 599–600 (3d Cir. 2000) (disclosures in a company's 10-Q filings were "more than sufficient" to put potential investors on notice of allegedly omitted material information).

Specifically, Ocugen's public filings provided that Ocugen "may be unable to successfully produce and commercialize a vaccine that effectively and safely treats [COVID-19] in a timely manner, if at all, and ultimately be unable to obtain EUA or BLA approval in the United States"

### 2. Material Misrepresentations

Because Plaintiff's "overarching omission" theory fails, the Court examines the fifteen statements alleged to determine whether any independently rise to the level of material misrepresentations. To begin, Plaintiff repeatedly takes issue with the projection that Ocugen would submit an EUA application in the first six months of 2021 and was generally progressing towards the goal of EUA approval. *See generally*, ECF No. 28; ECF No. 41-3 (statements 1, 4–11). However, it is only in hindsight that Defendants' projection for EUA submission in the first half of 2021, or indication that Ocugen was moving "full speed ahead" and "continu[ing] to make progress" towards submission, might be misleading. Though Defendants did not ultimately submit an EUA application in the first half of 2021, the Amended Complaint suggests that they took the steps necessary to do so (*i.e.* submitting a Master File in March 2021). ECF No. 28 at 82. On the facts pled, there is no basis to conclude that Defendants were not genuinely working towards this goal. Indeed, Plaintiff offers nothing to suggest that Defendants did not intend to submit an EUA

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in part because "[t]he regulatory pathway for COVAXIN is continually evolving" and because the "FDA may not accept data from the studies conducted with COVAXIN at clinical trial sites in India and may require us to conduct clinical studies in the United States." *See, e.g.*, ECF No. 41-36 ("Risk Factors" contained in Ocugen's March 2021 Form 10-K).

Similar disclosures were made at the beginning of investor calls: "Risks and uncertainties include . . . the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preliminary and the interim data," "unfavorable new clinical data," or data "subject to differing interpretations" by the scientific community[;]" whether "the FDA[] will be satisfied with the design and results from [clinical studies] of COVAXIN, which have been conducted by Bharat Biotech in India, whether and when any biologics license and/or emergency use authorization applications may be filed in the United States for COVAXIN; whether and when any such applications may be approved by the FDA; decisions by the FDA impacting labeling, manufacturing processes, safety, and/or other matters that could affect the availability or commercial potential of COVAXIN in the United States, including development of products or therapies by other companies." *See, e.g.*, ECF No. 41-23 at 3.

in the first half of 2021 at the time such statements were made, or that the FDA had communicated that Ocugen should not proceed towards an EUA submission. These statements, which rely upon hindsight, cannot support Plaintiff's claim. *Williams*, 869 F.3d at 244.

Additionally, vague statements indicating that Ocugen was making progress towards EUA submission, with the goal of EUA approval, were nothing more than immaterial puffery that any reasonable investor would understand as such. ECF No. 41-3 (statements 5, 6, 8, 10, 14); *In re Artana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 757–58 (S.D.N.Y. 2018) (claims of "remarkable progress" in advancing product toward "commercialization" and that company was "confident" about timeline for commercialization constitute puffery); *See In re EDAP TMS S.A. Sec. Litig.*, No. 14-cv-6096, 2015 WL 5326166, at *10 (Sept. 14, 2015) ("[S]tatements plac[ing] a positive spin on developments in the [FDA] process . . . constitute inactionable puffery and corporate optimism."). Accordingly, any projections as to the timing of EUA submission or statements regarding progress towards that goal do not support Plaintiff's claim.

Plaintiff also takes issue with Defendants' projection that they would distribute 100 million doses of COVAXIN in 2021 following EUA approval, but such statements were not material. ECF No. 41-3 (statements 2–6, 8). A reasonable investor would recognize the statements as puffery or corporate optimism, especially in the context of the COVID-19 pandemic and novel regulatory path towards EUA approval. *See Lungu v. Antares Pharma Inc.*, 2022 WL 212309, at *6 (Courts "must distinguish material representations [and objectively verifiable facts] from statements of opinion . . . or statements that 'constitute no more than puffery and are understood by reasonable investors as such.'" (quoting *EP Medsystems, Inc.*, 235 F.3d at 872)). Indeed, vaccine distribution

hinged upon several matters outside of Defendants' control[16] to which the American public was acutely attuned during the height of the pandemic. Indeed, Defendants' projections were purely speculative and dependent upon EUA approval in the first instance.[17] As articulated in the context of possible mergers that may or may not ultimately occur, the Supreme Court observed that Federal Securities law is not based on a "paternalistic" view of investors which assumes that investors are unable to appreciate "that mergers are risky propositions up until the closing." *Basic Inc.*, 485 U.S. at 234 (rejecting the bright line rule that possible mergers need not be disclosed until there is an agreement-in-principle). Similarly, in the height of an unprecedented global pandemic, reasonable investors would certainly appreciate that FDA approval and vaccine distribution was a "risky endeavor" even if Defendants omitted a caveat to this effect. Accordingly, any reasonable investor would be able to discern Defendants' projections related to vaccine distribution as immaterial puffery which cannot support Plaintiff's claim. *In re Aetna*, 617 F.3d at 283; *EP Medsystems, Inc.*, 235 F.3d at 875 (statements that are "obviously unimportant" may be immaterial as a matter of law). Moreover, such statements are classically forward-looking and, to the extent they were predated by adequate cautionary language, are covered by the PSLRA safe harbor.[18]

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[16] To name a few such factors: EUA approval, the speed at which manufacturers or third-party distributors could produce and deliver vaccines, and the availability and efficacy of other vaccines.

[17] Moreover, there is no indication that Defendants were not prepared to move forward and distribute 100 million doses of COVAXIN if the predicate and speculative step of EUA approval occurred.

[18] The PSLRA safe harbor applies, *inter alia*, to forward-looking statements that are identified as such and accompanied by meaningful cautionary statements. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d at 278. Inactionable forward-looking statements typically include "projections of future performance [and] plans and objectives for future operations." *Id.* The projection that Defendants aimed to distribute a specific number of vaccine doses in 2021 falls squarely within this definition. Additionally, cautionary statements disclosed in SEC filings may be incorporated by reference and do not have to be in the same document as the forward-looking statements, provided that the cautionary language is "extensive, specific, and directly related to the alleged misrepresentation." *Id.* at 282. Here, Ocugen's public filings cautioned that Ocugen may be

Additionally, Plaintiff alleges that Defendants' projection that the vaccine had potential for significant revenues was materially false and misleading. *See, e.g*, ECF No. 28 at 53; ECF No. 41-3 (statement 4). Yet courts have uniformly held that vague predictions related to revenue constitute immaterial puffery. *See, e.g.*, *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1427–28 (collecting cases). Therefore, Defendants' general projection of increased revenue is insufficient to maintain Plaintiff's claim as it would be understood as "obviously unimportant" puffery to a reasonable investor. *EP Medsystems, Inc.*, 235 F.3d at 875.

The lion's share of statements at issue—projections related to EUA submission, vaccine distribution, and potential profit—are insufficient to support Plaintiff's claim as described *supra*. ECF No. 41-3 (statements 1–6, 8, 10–11, 14). The five remaining statements require individualized discussion. *Id.* (statements 7, 9, 12, 13, 15). Each of these statements might arguably imply that Defendants received positive feedback or other non-public information from the FDA or represent Defendants' reading of FDA guidance. However, upon close review the Court finds that none of the remaining statements support Plaintiff's claim.

First, according to a *Reuters* article[19] published March 15, 2021, when asked about the FDA, Mr. Musunuri stated that "they're fine with the way the interim analysis is being done."[20]

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"unable to successfully produce and commercialize" COVAXIN "in a timely manner, if at all," based on uncertainties related to FDA approval. *See, e.g.*, ECF No. 41-36 at 6, 16 ("Risk Factors" contained in Ocugen's March 2021 Form 10-K).

[19] Plaintiff's reliance on the *Reuters* article suffers from an additional flaw because Mr. Musunuri's quoted statement does not explicitly reference the FDA; rather, it is the author who provides the necessary context for Mr. Musunuri's statement. Defendants cannot be held liable for statements they did not make and there is nothing in the Complaint to suggest that Defendants controlled the content of the report or affirmed that Mr. Musunuri's quote was not taken out of context. *See City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 172 (3d Cir. 2014) ("Defendants cannot be held responsible for statements they did not make").

[20] Defendants argue that this statement was made in reference to pediatric trials, which do not form the basis of this suit. Jan. 26, 2023 Hr'g. 40:14-41:25. The Court declines to take a position

ECF No. 28 at 69; ECF No. 41-3 (statement 7). However, there is nothing to suggest—or any true facts to establish—that the FDA was not "fine with" the interim analysis as of March 2021 because Plaintiff does not allege what the FDA actually communicated to Defendants. *Compare Reid v. Hemispherx Biopharma, Inc.*, No. 09-cv-5262, 2010 WL 11710594, *2 (E.D. Pa. Apr. 20, 2010) (plaintiffs sufficiently alleged that defendants affirmatively misrepresented the content of feedback received from the FDA), *and In re Viropharma Inc. Sec. Litig.*, 21 F. Supp. 3d 458, 471 (E.D. Pa. 2014) (failure to disclose the FDA's ultimate "conclusions" regarding the deficiencies in a clinical study was actionable), *with In re Sona Nanotech, Inc. Sec. Litig.*, 562 F. Supp. 3d 715, 725 –26 (C.D. Cal. 2021) (allegation that defendant misrepresented feedback on EUA application was not actionable because plaintiff "fail[ed] to allege what the FDA actually communicated" to defendant). In the absence of any allegations to the contrary, the Court cannot find that Plaintiff adequately alleged that Mr. Musunuri's assertion was indeed a misrepresentation at the time it was made.[21] *Williams*, 869 F.3d at 244; *CALPERS*, 394 F.3d at 145 (explaining that "unless plaintiffs in securities fraud actions allege facts supporting their contentions of fraud with the requisite particularity . . . they may not benefit from inferences flowing from vague or unspecific allegations—inferences that may arguably have been justified under a traditional Rule 12(b)(6) analysis." (citations omitted)).

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on this matter because the article was not provided by either party and, even if it were incorporated by reference, the article is ambiguous on this point.

[21] Even if allegations specifying the FDA's direct feedback to Defendants had been made, other courts in this circuit have found that "interim FDA feedback is not material because it does not express a binding agency decision and is subject to change." *See Paxton v. Provention Bio, Inc.*, No. 21-cv-11613, 2022 WL 3098236, at *13 (D.N.J. Aug. 4, 2022) (quoting *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 542); *see also In re Discovery Labs. Sec. Litig.*, 2006 WL 3227767, at *12 ("Given the complexity of these negotiations . . . the law does not require blow-by-blow disclosures of conversations with regulatory agencies.").

Second, Defendants' discussion of clinical trial diversity and Dr. Forrest's speculation that the data would be translatable to the EUA process during the March 31, 2021 fireside chat was immaterial. ECF No. 41-3 (statement 9). During the fireside chat, Defendants described the diversity of the Phase III participants who, though all were Indian, included a cross-section of participants with respect to age, weight, body mass index, underlying conditions, and social and economic circumstances. ECF No. 28 at 76. Indeed, the trial generally accounted for diversity metrics identified by the FDA other than race. *Id.* at 23 (the November 2020 guidance highlighted diversity of age, sex, race, and ethnicity). However, that the FDA placed importance on racial diversity was publicly available. 21 C.F.R. § 10.115(n). So too was the fact that COVAXIN trials were being conducted in India (and using Indian participants). ECF No. 28 at 54. Accordingly, Defendants' failure to expressly connect the dots between the guidance and the Company's practices does not give rise to a material omission. *See Sanofi*, 87 F. Supp. 3d at 543 (an omission, "considered in light of what was undisputedly publicly known" is not material if the omitted information is already available to the public (citations omitted)); *See Nobel Asset Mgmt. v. Allo Therapeutics, Inc.*, No. 04-cv-1030, 2005 WL 4161977, at *7 (D. Colo. Oct. 20, 2005) (that defendants did not "tell investors about the FDA's published regulatory guidelines and how they might affect the FDA's view of [defendants'] application" was not material because "[s]uch information was available to investors"). Moreover, that Defendants believed the data would be acceptable to the FDA was a statement of optimism and opinion,[22] particularly in context of the

[22] "Interpretations of clinical trial data are considered opinions" which are "only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." *City of Edinburgh Council*, 754 F.3d at 170; *In re Amarin Corporation PLC Sec. Litig.*, 2022 WL 2128560 at *132 (applying *City of Edinburgh Council* rather than *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175 (2015)). Here, Plaintiff does not allege that Defendants did not honestly believe that the Phase III trial data would be acceptable to the FDA. Instead, Plaintiff asks the Court to infer that Defendants' statements were not honestly believed. ECF No.

pandemic and the non-binding nature of the FDA's guidance, further indicating that this statement was immaterial. *In re Aetna*, 617 F.3d at 283.

Third, Plaintiff fails to establish that Mr. Musunuri's statement on the May 7, 2021 investor call that the FDA had not said anything "about wanting to see vaccine data for U.S. patients" before moving forward with the EUA application was a material misrepresentation as of that date. ECF No. 41-3 (statement 12). Specifically, the Amended Complaint does not contain factual allegations suggesting that the FDA had communicated otherwise to Defendants as of May 7, 2021. Plaintiff

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43 at 16–17. However, in light of the novel EUA process and unprecedented pandemic, the Court cannot find that such an inference is appropriate.

For similar reasons, even under the more rigorous *Omnicare* test, Plaintiff's claim is still unavailing. In *Omnicare*, the Supreme Court provided an instructive analogy: "In the context of the securities market, an investor, though recognizing that legal opinions can prove wrong in the end, still likely expects [the assertion "we believe our conduct is lawful"] to rest on some meaningful legal inquiry—rather than, say, on mere intuition, however sincere." *Omnicare, Inc.*, 575 U.S. at 189. However, "[r]easonable investors understand that opinions sometimes rest on weighing of competing facts." *Id.* at 189–90. For example, if one "did not disclose that a single junior attorney expressed doubts about a practice's legality, when six of his more senior colleagues gave a stamp of approval[,] [t]hat omission would not make the statement of opinion misleading, even if the minority position ultimately proved correct." *Id.* at 190. This is so because "[a] reasonable investor does not expect that *every* fact known to an issuer supports its opinion statement." *Id.* (emphasis original).

This analogy is instructive. Plaintiff does not allege any facts to indicate that Defendants entirely shirked due diligence in forming their opinion that the data would be acceptable to the FDA. Rather, even viewing the facts alleged in the light most favorable to Plaintiff, the only reasonable inference the Court can draw is that Defendants attempted to satisfy many of the non-binding guidelines on an accelerated timeline and incorrectly (though not unjustifiably) believed this would result in an EUA. Though statements of opinion by corporate officials "can be materially significant to investors because investors know that these top officials have knowledge and expertise far exceeding that of an ordinary investor," *In re Burlington Sec. Litig.*, 114 F.3d at 1428, this rationale is significantly dampened by the context of the pandemic. Indeed, confronted with a global pandemic and the seldom used EUA approval process, a reasonable investor would appreciate that Defendants' position was nuanced. *See Omnicare*, 575 U.S. at 190. This is buttressed by the fact that, in the context of EUA applications, clinical trial data was only considered "if available" and the demographic representation required of each trial was not required by statute. 21 U.S.C. § 360bbb–3(c)(3). Indeed, FDA guidance only "encourage[d]" diversity but in no way was it mandated. *See* ECF No. 41-15 at 15.

relies on hindsight to color this statement as misrepresentative or false, but such allegations are not enough to support Plaintiff's claim. *Williams*, 869 F.3d at 244; *CALPERS*, 394 F.3d at 145.

Fourth, Mr. Musunuri's statement on the same investor call that Defendants were "following FDA guidance on EUA[s]" was not misleading when read in context. ECF No. 41-3 (statement 13). Plaintiff's selective quote ignores the context of the conversation: Mr. Musunuri was asked to describe the difference between submitting a Master File and EUA application. ECF No. 41-23 at 8. Accordingly, he provided that "based on the guidance," the Master File included "all preclinical manufacturing and any other data" prior to Phase III which "gives an opportunity for [the] FDA to review and provide additional comments prior to [Defendants] filing an EUA." *Id.* Then, "the second step is filing the [EUA] application." *Id.* Read in context, it is evident that Mr. Musunuri's statement that Defendants were "following FDA guidance" was narrowly describing the procedure required and was not in reference to every minute component of all (non-binding) FDA guidance provisions. Plaintiff's "selective reading" of this statement cannot support his claim. *See City of Edinburgh Council*, 754 F.3d at 168 (citing *Tellabs, Inc.*, 551 U.S. at 322).

Finally, Dr. Forrest's statement in the May 26, 2021 press release was not material. In the press release, Dr. Forrest provided that he read the guidance to "refer[] specifically to vaccines based on the spike protein" rather than inactivated virus vaccines such as COVAXIN. ECF No. 43 at 25; ECF No. 41-3 (statement 15). Though the bulk of the May 25, 2021 guidance did not differentiate between vaccine types, an appendix attached to the guidance did make such a distinction. ECF No. 41-20 at 22. Specifically, the appendix addressed concerns about reduced efficacy against variants as to previously authorized spike protein vaccines. *Id.* at 22. Read in context, Dr. Forrest's statement clearly addresses the appendix rather than the full guidance. Indeed, he provides that COVAXIN "provides a broadly protective immune response beyond the

spike protein, *offering potential effectiveness against multiple existing and emerging variants* and reducing the possibility of mutant virus escape." ECF No. 44-7 (emphasis added). A "selective reading" of this statement does not support Plaintiff's claim. *See City of Edinburgh Council*, 754 F.3d at 168 (citing *Tellabs, Inc.*, 551 U.S. at 322). Additionally, Plaintiff does not allege that Mr. Musunuri's statement in the same press release that Defendants had "been in discussions with the FDA since [the year prior]" was incorrect or misleading when made.[23] ECF No. 28 at 87. Accordingly, because Plaintiff fails to allege any statements or omissions which are both material and misleading, Count I must be dismissed as to Plaintiff's 10b5-(b) claim.

**b. Section 10(b) of the Exchange Act and Rule 10b-5(a) & (c) Claims (Count I)**

Plaintiff also alleges liability under Rule 10b-5(a) and (c). ECF No. 28 at 112. Under Rule 10b-5(a) it is unlawful to "employ any device, scheme, or artifice to defraud" in connection with the purchase or sale of any security. 17 C.F.R. § 240.10b-5(a). Pursuant to Rule 10b-5(c), it is unlawful to "engage in any act, practice or course of business which operates or would operate as a fraud or deceit upon any person" in connection with the purchase or sale of any security. 17 C.F.R. § 240.10b-5(c). Though liability under Rules 10b-5(a) and (c) may attach despite dismissing a 10b-5(b) claim, as a baseline the conduct supporting 10b-5(a) or (c) claims must involve statements that qualify as false or misleading or must involve entirely separate conduct apart from the statements supporting a 10b-5(b) claim. *See Lorenzo v. SEC*, 139 S.Ct. 1094, 1102–03 (2019) (holding that those who do not "make" the false statements, but instead disseminate the *same* false statements, can be found to have violated Rule 10b-5(a) and (c) even when the 10b-5(b) claim was dismissed). Here, however, Plaintiff's 10b-5(a) and (c) claims rest entirely on the

[23] As discussed *supra*, Plaintiff does not allege when and to what extent Defendants' communication with the FDA was insufficient.

same statements alleged as to Rule 10b-5(b). Indeed, Plaintiff does not allege any deceptive or fraudulent acts, scheme, or practices separate from the fifteen statements alleged. Accordingly, because Plaintiff fails to allege any material misstatements or omissions as described *supra* and also fails to allege any other conduct giving rise to liability beyond the alleged statements, his claims pursuant to Rule 10b-5(a) and (c) must also be dismissed and Count I will be dismissed in its entirety.

**c. Section 20(a) of the Exchange Act and Rule 20A Claims (Counts II and III)**

In Counts II and III, Plaintiff alleges control person liability against Individual Defendants and insider trading against Mr. Musunuri, respectively. ECF No. 28 at 113–14. Section 20(a) of the Securities Exchange Act of 1934 creates a cause of action against individuals who exercise control over a "controlled person," including a corporation, that has committed a violation of Section 10(b). 15 U.S.C. § 78t(a). Accordingly, "liability under Section 20(a) is derivative of an underlying violation of Section 10(b) by the controlled person." *Avaya, Inc.*, 564 F.3d at 252. Thus, if the underlying primary violation of federal securities law is insufficiently alleged, the Section 20(a) claim fails as well. *See id.* at 280. Likewise, Section 20A provides a private right of action for insider trading violations and requires pleading a predicate violation of the Exchange Act. *City of Edinburgh Council*, 754 F.3d at 175. Again, a Section 20A claim is viable only insofar as a primary violation of the Exchange Act has been alleged. *Id.* Here, because the Court finds dismissal of Count I appropriate, Counts II and III must also be dismissed.

## VI. CONCLUSION

For the reasons set forth above, Defendants' Motion to Dismiss (ECF No. 41) will be granted and this case will be dismissed with prejudice.[24]

**BY THE COURT:**

**/s/ Chad F. Kenney**

**CHAD F. KENNEY, JUDGE**

[24] The PSLRA narrows the impact of Rule 15(a)'s directive to freely allow leave to amend. *CALPERS*, 394 F.3d at 165. Indeed, "[a]llowing leave to amend where there is a stark absence of any suggestion by the plaintiffs that they have developed any facts since the action was commenced, which would, if true, cure the defects in the pleadings under the heightened requirements of the PSLRA would frustrate Congress's objective in enacting this statute of providing a filter at the earliest stage (the pleading stage) to screen out lawsuits that have no factual basis." *Id.* (citations omitted).

This case was commenced in June 2021 and an Amended Complaint was filed one year later in June 2022. ECF Nos. 1, 28. This Motion was briefed throughout Summer and Fall 2022 and argued in January 2023. ECF Nos. 41, 43, 44, 50. However, throughout the pendency of this case Plaintiff has not suggested any factual development that might cure the deficiencies outlined above. Importantly, Plaintiff's claims largely fail as a matter of law rather than because of insufficient pleadings. While the Court has identified two categories of allegations which might benefit from additional pleadings—the extent and content of communication with the FDA and whether Defendants indeed intended to submit an EUA application—there is nothing to suggest that Plaintiff has developed any facts on these limited issues since the commencement of this action that might save his claims. The Court therefore denies Plaintiff's request to file a second amended complaint.